SUPERIOR COURT OF NEW JERSEY

CHAMBERS OF
JESSICA R. MAYER, J.S.C.
JUDGE

MIDDLESEX COUNTY COURTHOUSE
P.O. BOX 964
NEW BRUNSWICK, NEW JERSEY 08903-964

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Memorandum of Decision on Defendant's Motions for Partial Summary Judgment as to Plaintiffs' Claims for Design Defect

In Re: AlloDerm® Litigation, Case Code 295

Michael Simineri and Karen Simineri v. LifeCell Corporation

Docket No. MID-L-5972-11 CM

Debbie Foster and David Foster v. LifeCell Corporation

Docket No. MID-L-6841-12 CM

Patricia Julien v. LifeCell Corporation

Docket No. MID-L-597-12 CM

Thomas Dutcher v. LifeCell Corporation

Docket No. MID-L-1469-12 CM

Dated August 14, 2015

For Plaintiffs: Lawrence R. Cohan, Esq., Adrianne W. Webb, Esq., Joseph J. Fantini, Esq., Paola Saneaux, Esq., Sol H. Weiss, Esq., Anapol Schwartz.

For Defendant: David W. Field, Esq., Stephen R. Buckingham, Esq., Joseph A. Fischetti, Esq., Lowenstein Sandler LLP.

Defendant LifeCell Corporation ("Defendant" or "LifeCell") moves for summary judgment as to the claims asserted by each of the bellwether Plaintiffs, Michael and Karen Simineri, Debbie and David Foster, Thomas Dutcher, and Patricia Julien. (collectively "Plaintiffs"), alleging that LifeCell's product, AlloDerm®, is defectively designed for use in abdominal hernia repairs. Because Defendant's motions and the Plaintiffs' oppositions as to each

plaintiff raise substantially the same arguments and issues, the court will address the motions collectively. The court will address the facts and arguments specific to individual plaintiffs where necessary. In addressing Defendant's motions, the court reviewed the parties' filed submissions and the written arguments of counsel.[1] Counsel for the parties waived oral argument on Defendant's design defect motions and consented to the court's disposition of these matters on the papers. The following memorandum of decision sets forth the court's disposition of Defendant's motions.

I. Background

A. AlloDerm®

LifeCell manufactures AlloDerm®, a type of soft tissue graft known as reconstructive tissue matrix.[2] AlloDerm® is made from minimally processed human cadaver skin.[3] AlloDerm® was developed in the 1990s and was initially used to treat burn victims.[4] Later, AlloDerm® was marketed by LifeCell and used by surgeons for a variety of other uses, including rotator cuff, dental implant, and breast reconstruction surgeries.[5] In the late 1990s, some surgeons began using AlloDerm® in complex hernia repair surgeries.[6] After learning that surgeons were using AlloDerm® for complex hernia repairs, LifeCell began marketing AlloDerm® for that purpose.[7]

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[1] Counsel agreed that all pending cases against LifeCell are governed by New Jersey law. See Consent Order dated January 15, 2015.
[2] Defendant's Brief in Support of the Motion for Summary Judgment as to Plaintiffs Michael and Karen Simineri's Product Liability Claim Based on Design Defect ("Def.'s Simineri Br.") 1.
[3] Plaintiff Michael Simineri's Opposition to Defendant's Motion for Summary Judgment ("Simineri Opp.") 2.
[4] Def.'s Simineri Br. 1.
[5] Simineri Opp. 2.
[6] Ibid.
[7] Ibid.

B. Ventral Incisional Hernias

Ventral hernias are the most common form of abdominal wall hernias.[8] The most common type of ventral hernias are known as incisional hernias, which form in the abdominal wall at the site of a previous surgical incision.[9] There are a number of ways to repair a ventral incisional hernia, including primary repair, synthetic mesh repair, and biologic graft repair.[10] Primary repair involves simply suturing together the edges of the hernia defect in the abdominal wall.[11] Primary repair is most suitable for smaller hernias as the recurrence rate can be high in patients with larger defects.[12]

According to one of Plaintiffs' experts, Dr. Roger Huckfeldt, synthetic mesh is the most common product used for surgical hernia repairs.[13] Synthetic meshes are made from materials such as nylon or prolene and are placed in the abdominal wall to reinforce the hernia repair.[14] Synthetic meshes offer an inexpensive and effective hernia repair.[15] However, synthetic meshes are not without complications.[16] For example, complications associated with the use of synthetic meshes include the formation of adhesions between the mesh and the intra-abdominal organs, erosion of the mesh, and infection.[17] Because infections in the presence of synthetic meshes are difficult to treat, synthetic meshes are contraindicated for use in contaminated environments.[18] In the event of

[8] Fantini Simineri Cert., Ex. F, Dr. Roger Huckfeldt General Causation Report ("Huckfeldt General Report") 1.
[9] Id. at 1-2.
[10] Id. at 3-4.
[11] Ibid.
[12] Id. at 4.
[13] Ibid.
[14] Ibid.
[15] Ibid.
[16] Ibid.
[17] Ibid.
[18] Ibid.

an infection at the site of a synthetic mesh repair, the mesh must be surgically removed from the patient (known as "explantation") and the hernia repaired with alternative methods.[19]

Biologic graft implants are an alternative to the use of synthetic mesh.[20] Because biologic grafts cause less foreign body response, the use of biologic implants reduces the risks of adhesions and infections.[21] Biologic graft implants vary in design. For example, biologic grafts can be made from either animal tissue (xenograft) or from human tissue (allograft).[22] Additionally, biologic grafts can be either cross-linked or non-cross-linked.[23] Cross-linking refers to chemically treating the biologic graft in order to link together the proteins in the tissue, thus increasing the strength of the graft.[24] Although cross-linking can increase the strength of a biologic graft, the process also increases the risk of foreign body response, resulting in a higher risk of adhesions, scarring, and infection complications.[25] AlloDerm® is an example of a non-cross-linked, human-tissue-based biologic graft.[26]

All four bellwether Plaintiffs had incisional hernias repaired with AlloDerm®. All four Plaintiffs had hernia recurrence, and required additional surgery. Plaintiffs brought suit under the New Jersey Products Liability Act, N.J.S.A. § 2A:58C-1 et seq., alleging that AlloDerm® was defectively designed[27] and unfit for use in abdominal hernia repairs due to a tendency to thin and

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[19] Ibid.
[20] Ibid.
[21] Ibid.
[22] Id. at 5.
[23] Ibid.
[24] Ibid.
[25] Field Foster Reply Cert., Ex. F, Huckfeldt Dep. 165:18-167:12.
[26] Huckfeldt General Report 5.
[27] Defendant has also filed separate motions for summary judgment as to all four plaintiffs' failure-to-warn claims. Those motions are addressed in separate opinions by the court.

stretch, leading to abdominal bulging and eventual hernia recurrence, necessitating additional surgeries.[28]

C. Plaintiffs' Relevant Medical Histories

i. Plaintiff Michael Simineri

Plaintiff Michael Simineri is a 54-year old man with a history of obesity, hypertension, high blood pressure, and diabetes, all factors that potentially complicate hernia repair.[29] In 2005, Mr. Simineri was diagnosed with a small ventral incisional hernia at the site of a 2002 gastric bypass surgery.[30] The hernia was primarily repaired with sutures only.[31] Two years later, Mr. Simineri was diagnosed by Dr. Gerardo Garcia with a recurrent incisional hernia as well as gallstones.[32] Dr. Garcia decided to perform a laparoscopic cholecystectomy to remove the gallstones, to be immediately followed by a ventral hernia repair surgery.[33] Dr. Garcia used AlloDerm® instead of a synthetic mesh to reinforce Mr. Simineri's hernia repair due to the risk of infection inherent in the simultaneous cholecystectomy.[34] In April of 2010, Mr. Simineri returned to Dr. Garcia complaining of a painful bulge that he first noticed after doing some lifting at work.[35] Mr. Simineri was again diagnosed with a recurrent incisional hernia.[36] In January of 2011, Dr. Garcia repaired the hernia with a synthetic mesh because there was no risk of infection at the time.[37] Mr. Simineri has not suffered another hernia recurrence to date.[38]

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[28] Foster Opp. 5.
[29] Def.'s Simineri Br. 2.
[30] Simineri Opp. 4.
[31] Ibid.
[32] Ibid.
[33] Ibid.
[34] Ibid.
[35] Ibid.; Field Simineri Cert., Ex. K.
[36] Simineri Opp. 4-5.
[37] Id. at 5.
[38] Ibid.

ii. Plaintiff Thomas Dutcher

Plaintiff Thomas Dutcher is a 52-year-old man with a history of morbid obesity.[39] Shortly after undergoing gastric bypass surgery in 2003, Mr. Dutcher developed a ventral incisional hernia which was repaired with a synthetic mesh in February of 2004.[40] Following the hernia repair, Mr. Dutcher developed a wound infection with persistent drainage of purulent material that was treated unsuccessfully with antibiotics.[41] In April of 2005, due to the persistent infection, Mr. Dutcher underwent surgical explantation of the infected synthetic mesh as well as another hernia repair. For this surgery, Dr. Jeffrey Hunter used AlloDerm® to reinforce Mr. Dutcher's hernia repair because the presence of infection foreclosed the use of a synthetic mesh.[42] In September of 2005, a CT scan revealed Mr. Dutcher suffered a recurrent incisional hernia.[43] In March of 2008, Mr. Dutcher's recurrent hernia was repaired using another synthetic mesh, as the infection had cleared by that time.[44] Mr. Dutcher has not experienced another hernia recurrence to date.[45]

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[39] Defendant's Brief in Support of the Motion for Summary Judgment as to Plaintiff Thomas Dutcher's Product Liability Claim Based on Design Defect. ("Def.'s Dutcher Br.") 2.
[40] Ibid.
[41] Plaintiff Thomas Dutcher's Opposition to Defendant's Motion for Summary Judgment ("Dutcher Opp.") 2.
[42] Def.'s Dutcher Br. 3.
[43] Dutcher Opp. 2.
[44] Id. at 3.
[45] Ibid.

iii. Plaintiff Debbie Foster

Plaintiff Debbie Foster is a 62-year-old woman who first underwent ventral hernia repair in February of 2001.[46] Ms. Foster has a history of morbid obesity and chronic obstructive pulmonary disease, among other health problems.[47] In 2007, following a gastric bypass revision surgery the previous year, Debbie Foster underwent her second ventral hernia repair.[48] Both the 2001 and 2007 hernias were repaired using synthetic meshes.[49] In June of 2008, due to an infection at the surgical site, Dr. Samir Gupta surgically explanted the two infected synthetic meshes and repaired Ms. Foster's third hernia using AlloDerm®.[50] Six months later, in December of 2008, Ms. Foster was again diagnosed with a small ventral hernia. That hernia was left untreated,[51] and in June of 2009, Ms. Foster was diagnosed with an incarcerated incisional hernia.[52] Nearly two years later, in April of 2011, Ms. Foster had a fourth hernia repair which was reinforced using a synthetic mesh as there was no infection present at the time.[53] In April of 2012, Ms. Foster underwent her fifth ventral hernia repair, again using a synthetic mesh.[54] Since the April 2012 repair, Ms. Foster has not undergone any additional hernia repair.[55]

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[46] Plaintiff Debbie Foster's Opposition to Defendant's Motion for Summary Judgment ("Foster Opp.") 6.
[47] Defendant's Brief in Support of the Motion for Summary Judgment as to Plaintiffs Debbie and David Foster's Product Liability Claim Based on Design Defect ("Def.'s Foster Br.") 1.
[48] Foster Opp. 6.
[49] Ibid.
[50] Ibid.
[51] Def.'s Foster Br. 4.
[52] Ibid.
[53] Ibid.
[54] Ibid.
[55] Ibid.

iv. Plaintiff Patricia Julien

Plaintiff Patricia Julien is a 68-year-old retired woman who, in 2004, underwent successful surgery to treat a bowel obstruction.[56] In late 2005, Ms. Julien was diagnosed with a ventral incisional hernia.[57] In January of 2006, Ms. Julien saw Dr. Joubin Khorsand, who repaired Ms. Julien's incisional hernia with the use of AlloDerm®.[58] Dr. Khorsand decided to use AlloDerm® due to the location of the hernia and the potential of infection if there were bowel fluids in the hernia area.[59] In August of 2007, a CT scan identified laxity at the site of her 2006 hernia repair as well as an inflamed appendix.[60] In 2007, during a surgery to remove the inflamed appendix, Dr. Khorsand observed laxity in Ms. Julien's hernia repair.[61] In August of 2009, Dr. Khorsand diagnosed Ms. Julien as having a recurrent incisional hernia.[62] In June of 2010, Ms. Julien underwent another hernia repair in which Dr. Khorsand used a synthetic mesh.[63] Ms. Julien has not suffered a hernia recurrence since that time.[64]

D. Defendant's Motions for Summary Judgment

The core of LifeCell's argument in favor of summary judgment on Plaintiffs' design-defect claims is that a plaintiff in a design defect case is required under New Jersey law to prove the existence of a safer alternative design. LifeCell contends Plaintiffs' evidence is insufficient to

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[56] Plaintiff Patricia Julien's Opposition to Defendant's Motion for Summary Judgment ("Julien Opp.") 6.
[57] Ibid.
[58] Ibid.
[59] Defendant's Brief in Support of the Motion for Summary Judgment as to Plaintiff Patricia Julien's Product Liability Claim Based on Design Defect ("Def.'s Julien Br.") 2.
[60] Julien Opp. 6-7.
[61] Id. at 7.
[62] Def.'s Julien Br. 6.
[63] Julien Opp. 7.
[64] Ibid.

establish that a safer alternative design existed at the time of their respective surgeries.[65] LifeCell argues that Plaintiffs' experts offering opinions on safer alternative designs—Drs. Roger Huckfeldt and Kristen Billiar—"lack any basis to opine and have offered no empirical evidence that their alleged alternatives were known to be safer than AlloDerm" at the time of Plaintiffs' surgeries.[66]

E. Plaintiffs' Oppositions

Plaintiffs raise several arguments in opposition to LifeCell's motions. First, Plaintiffs argue they are not required to prove a safer alternative design under New Jersey law. Plaintiffs believe they can prove their design defect claims by demonstrating either a safer alternative design or that the risks of AlloDerm® outweighed its benefits.[67] Second, Plaintiffs contend that they have produced sufficient evidence to demonstrate that safer alternative designs existed at the time of Plaintiffs' surgeries.[68] Plaintiffs argue that they are "not required to show that the safety of the alternative designs was known [at the time of Plaintiffs' surgeries]–only that the alternative designs themselves were practical and feasible at that time."[69] Finally, Plaintiffs posit that "the lack of any design by Defendant with regard to AlloDerm for abdominal hernia repair is itself a design defect."[70] In essence, Plaintiffs argue that LifeCell's marketing of AlloDerm® for use in hernia repairs without altering the design of the product or conducting sufficient testing to determine if the design was appropriate for use in hernia repairs itself renders AlloDerm® defective.

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[65] As LifeCell notes in its motion papers, the safer alternative design must have existed at the time of manufacture. Lewis v. Am. Cyanamid Co., 155 N.J. 544, 565 (1998). For the purposes of these motions, the parties are relying on the date of the bellwether plaintiffs' surgeries as a proxy for the date of manufacture. LifeCell reserved the right to rely on the actual manufacture dates at the time of trial. See Def.'s Dutcher Br. 5, n.3.
[66] Def.'s Dutcher Br. 19.
[67] Dutcher Opp. 15.
[68] Id. at 19.
[69] Ibid.
[70] Id. at 23.

II. Legal Analysis

A. Summary Judgment Standard

"A party seeking any affirmative relief may . . . move for a summary judgment or order on all or any part thereof or as to any defense." R. 4:46-1. Summary judgment or an interlocutory order may be granted as to "any issue in the action . . . although there is a genuine factual dispute as to any other issue . . . ." R. 4:46-2(c). Summary judgment is appropriate if "the pleadings, depositions, answers to interrogatories and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact challenged and that the moving party is entitled to a judgment or order as a matter of law." Ibid. In considering a motion for summary judgment, the court should determine whether "the competent evidential materials presented, when viewed in the light most favorable to the non-moving party, are sufficient to permit a rational factfinder to resolve the alleged disputed issue in favor of the non-moving party." Brill v. Guardian Life Ins. Co. of Am., 142 N.J. 520, 540 (1995). "If there exists a single, unavoidable resolution of the alleged disputed issue of fact, that issue should be considered insufficient to constitute a 'genuine' issue of material fact for purposes of Rule 4:46-2." Ibid.

B. Design Defect Under the New Jersey Products Liability Act

Under the New Jersey Products Liability Act ("NJPLA"), N.J.S.A. 2A:58C-1, et seq., a manufacturer is liable for injuries caused by a product that is "not reasonably fit, suitable or safe for its intended purpose because it . . . was designed in a defective manner." N.J.S.A. 2A:58C-2(c). Whether a product is defectively designed is determined by a "'risk-utility' analysis under which a manufacturer is held liable only 'if the danger posed by the product outweighs the benefits of the way the product was designed and marketed.'" Truchan v. Nissan Motor Corp. in U.S.A.,

316 N.J. Super. 554, 563 (App. Div. 1998) (quoting Johansen v. Makita U.S.A., Inc., 128 N.J. 86, 95 (1992)). Traditionally, the risk-utility analysis of a product examined seven factors:

> (1) The usefulness and desirability of the product – its utility to the user and to the public as a whole.
>
> (2) The safety aspects of the product – the likelihood that it will cause injury, and the probable seriousness of the injury.
>
> (3) The availability of a substitute product which would meet the same need and not be as unsafe.
>
> (4) The manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility.
>
> (5) The user's ability to avoid danger by the exercise of care in the use of the product.
>
> (6) The user's anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions.
>
> (7) The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance.
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> [Cepeda v. Cumberland Engineering Co., 76 N.J. 152, 174 (1978), (quoting John W. Wade, On the Nature of Strict Tort Liability For Products, 44 Miss. L.J. 825, 837-38 (1973)) overruled in part, Suter v. San Angelo Foundry & Machine Co., 81 N.J. 150 (1979)]

Under this seven-factor analysis, the plaintiff bore "the burden of both going forward with the evidence and of persuasion that the product contained a defect. To establish a *prima facie* case, the plaintiff should adduce sufficient evidence on the risk-utility factors to establish a defect." O'Brien v. Muskin Corp., 94 N.J. 169, 185 (1983), superseded by statute, New Jersey Products Liability Act, 1987 N.J. Laws 1076, as recognized in Roberts v. Rich Foods, 139 N.J. 365, 375 (1995).

However, consistent with the developing case law on design defect claims in New Jersey, "[a] plaintiff asserting a design defect in a products liability action 'must prove under a risk-utility analysis the existence of an alternate design that is both practical and feasible,' and 'safer' than

that used by the manufacturer." Diluzio-Gulino v. Daimler Chrysler, 385 N.J. Super. 434, 438 (App. Div. 2006) (quoting Lewis v. Am. Cyanamid Co., 155 N.J. 544, 571 (1998)). Thus, the existence of a safer alternative design is now an element of a plaintiff's *prima facie* case. Except in the rare case of a product that is "so dangerous and of such little use that under the risk-utility analysis [the] manufacturer [should] bear the cost of liability of harm to others," the plaintiff bears the burden of proving the existence of a practical and feasible safer alternative design. Smith v. Keller Ladder Co., 275 N.J. Super. 280, 283–84 (App. Div. 1994) (alterations in original) (quoting O'Brien, supra, 94 N.J. at 184).

A plaintiff's burden of proving a feasible and safer alternative design requires expert testimony. See Jones v. Synthes U.S.A. Sales, Inc., 2010 U.S. Dist. LEXIS 85744 (D.N.J. 2010). "Expert testimony in conclusionary terms is insufficient to meet that burden." Diluzio-Gulino, supra, 385 N.J. Super. at 438. Although the level of evidence required to prove a safer alternative design will vary depending on the circumstances of a particular case, in cases involving complicated products or design specifications, the expert's opinion must be supported by empirical evidence or specific data to provide the jury with a reasonable basis for concluding that a plaintiff's proposed alternative is actually safer than the allegedly defective product. See id. at 438–39; cf. Rider v. Twp. Of Freehold, 2008 N.J. Super. Unpub. LEXIS 641 (App. Div. 2008).

C. Plaintiffs Bear the Burden of Proving the Existence of a Safer Alternative Design

Under New Jersey Law, Plaintiffs are required to prove that a safer alternative design existed at the time of their surgeries. Plaintiffs mistakenly argue that they can prove a design defect through one of two separate methods of analysis: either by proving the existence of a safer alternative design or through a risk-utility analysis by demonstrating that the risks of AlloDerm®

outweigh its benefits.[71] However, Plaintiffs fail to recognize that the existence of a safer alternative design is simply one element of the traditional risk-utility analysis, not a theory of recovery separate and apart from the risk-utility analysis. Under New Jersey case law and the NJPLA, the existence of a safer alternative design is an element of Plaintiffs' *prima facie* claim for design defect.

In support of their risk-utility argument, Plaintiffs cite O'Brien v. Muskin Corp., discussing the seven factors relevant to a risk-utility analysis. O'Brien, supra, 94 N.J. at 182. However, the O'Brien court went on to explain that:

> The assessment of the utility of a design involves the consideration of available alternatives. If no alternatives are available, recourse to a unique design is more defensible. The existence of a safer and equally efficacious design, however, diminishes the justification for using a challenged design.
>
> [Id. at 184 (emphasis added)]

According to well-settled case law, the plaintiff bears the burden of proving a safer alternative design. Cavanaugh v. Skil Corp., 164 N.J. 1, 16-17 (1999) (explaining that design defect claims turn on proof of a feasible alternative design); Lewis, supra, 155 N.J. at 570 ("Plaintiffs who assert that the product could have been designed more safely must prove under a risk-utility analysis the existence of an alternative design that is both practical and feasible."); Truchan, supra, 316 N.J. Super. at 564 ("A plaintiff must generally prove that the product 'could have been designed in an alternative manner so as to minimize or eliminate the risk of harm.'" (quoting Lewis, supra, 155 N.J. at 570)); Smith, supra, 275 N.J. Super. at 284 ("[U]nless there is some basis for a jury to find that the risks involved in a product's use outweigh its utility even though there is no reasonably feasible alternative design, a plaintiff in a design-defect case is required to show the existence of

[71] Foster Opp. 10.

'a safe and reasonably feasible alternative to [the] defendant's product.'" (quoting Macri v. Ames McDonough Co., 211 N.J. Super. 636, 641 (App. Div. 1986)) (emphasis added)(alterations in original)). It is only where the product in question is egregiously dangerous and of so little use that a plaintiff escapes the burden of proving a safer alternative design.

The enactment of the NJPLA "drastically changed the method of analyzing product-liability cases." Roberts v. Rich Foods, 139 N.J. 365, 377 (1995). In O'Brien, a pre-NJPLA case, the court explained that "[a]lthough state-of-the-art evidence may be dispositive on the facts of a particular case, it does not constitute an absolute defense apart from risk-utility analysis." O'Brien, supra, 94 N.J. at 183. However, the NJPLA "converted into absolute affirmative defenses what had been under the common law merely factors in the overall risk-utility analysis." Roberts, supra, 139 N.J. at 377. Under the NJPLA, "the manufacturer or seller shall not be liable if . . . there was not a practical and technically feasible alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of the product." N.J.S.A. § 2A:58C-3(a)(1). This is known as the state-of-the-art defense and is subject to only one exception. Where the defendant manufacturer proves there was no practical and technically feasible alternative design, the manufacturer will not be liable unless the plaintiff proves by clear and convincing evidence that:

> (1) The product is egregiously unsafe or ultra-hazardous;
>
> (2) The ordinary user or consumer of the product cannot reasonably be expected to have knowledge of the product's risks, or the product poses a risk of serious injury to persons other than the user or consumer; and
>
> (3) The product has little or no usefulness.
>
> [N.J.S.A. § 2A:58C-3(b) (emphasis added); see also Roberts, supra, 139 N.J. at 379 (holding that where the defendant proves an absolute defense under the NJPLA, the plaintiff bears the burden of proving that the exception precludes the defendant's use of the defense).]

A defendant in a design defect case is not required to raise the state-of-the-art defense and may instead choose to attack the practicality of a plaintiff's proposed alternative design. See Cavanaugh v. Skil Corp., 164 N.J. 1, 17-18 (1999). Thus, the NJPLA shields a manufacturer from liability where there is no practical and technically feasible alternative design and places the burden on plaintiff to prove the existence of a design defect. The NJPLA makes it clear that even in cases where the defendant declines to raise the state-of-the-art defense, the plaintiff must prove either the existence of a reasonable alternative design or, that even though no safer alternative existed, the product was so egregiously dangerous and of so little use that the manufacturer should nonetheless be held liable. See Cavanaugh, supra, 164 N.J. 1; N.J.S.A. § 2A:58C-3. Proving the "egregiously unsafe" exception is an extremely high bar. Roberts v. Rich Foods, 139 N.J. 365, 375 (1995)(The section 3b exception applies to certain egregiously unsafe or ultrahazardous products that have hidden risks or could seriously injure third persons, and have little or no usefulness. ... However, [i]t is intended that such a finding would be made only in genuinely extraordinary cases-for example, in the case of a deadly toy marketed for use by young children, or of a product marketed for use in dangerous criminal activities." (alteration in original)(internal citations and quotations omitted)).

This is not a case where the product is so egregiously dangerous and of so little use that Plaintiffs may prove a design defect without proving the existence of a safer alternative design. Plaintiffs concede that AlloDerm® is not of so little use that it never should have been placed on the market. Plaintiffs further concede that AlloDerm® is appropriate for use in the treatment of burn victims.[72] Additionally, Plaintiffs' own experts have opined that even for hernia repair, AlloDerm® is useful in certain circumstances. Plaintiffs' expert, Dr. Gregory Dumanian, conceded

[72] Dutcher Opp. 19.

in his expert report that although he questions the use of AlloDerm® in some hernia repairs, "[t]hat is not to say that a small subset of patients did not benefit in some way by temporarily closing an abdominal wall defect in some contaminated situations with questionable soft tissue for closure."[73] Further, Plaintiffs' expert, Dr. Thomas Gouge, acknowledged that he still uses AlloDerm® in staged hernia repairs.[74]

Plaintiffs have failed to put forward sufficient evidence to demonstrate that AlloDerm® is so dangerous and of so little use such that Plaintiffs are excused from the burden of proving a safer alternative design. Based on an apparent misunderstanding of the case law, Plaintiffs state that "[b]ecause of and in reliance on Defendant's motion," Plaintiffs are "not asserting uncontroverted facts to show there is a genuine issue of material fact as to whether the risks of AlloDerm outweigh its utility in the setting of abdominal hernia repair."[75] Plaintiffs also mistakenly argue that proof of a safer alternative design is a separate theory from the risk-utility analysis. The law in New Jersey provides that in all but the most unusual cases, proof of a safer alternative design is a necessary element of the risk-utility analysis. Because this is not one of the unusual cases where the product in question is egregiously dangerous and totally devoid of utility, Plaintiffs bear the burden of proving a safer alternative design existed at the time of Plaintiffs' surgeries.

D. Failure to Test a Product, Standing Alone, is Not a Design Defect

Plaintiffs also argue that "the lack of any design by Defendant with regard to AlloDerm® for abdominal hernia repair is itself a design defect."[76] Dr. Kristen Billiar, a biomechanical

[73] Field Reply Cert., Ex. E, Dumanian Expert Report 27.
[74] Field Reply Cert., Ex. G, Gouge Dep. 41:5-8.
[75] Simineri Opp. 11.
[76] Dutcher Opp. 23.

engineer from the Worcester Polytechnic Institute and one of Plaintiffs' design-defect experts, opined in his export report that:

> It is my opinion, to a reasonable degree of scientific certainty, that AlloDerm is not appropriate for use in ventral/incisional hernia repair. The complete lack of design of AlloDerm for this high load-bearing application is a design defect. Further, LifeCell did not perform pre-clinical and clinical testing to determine optimal surgical techniques or to determine if AlloDerm was appropriate for the application with acceptable complication rates. Had LifeCell performed basic evaluation of AlloDerm when proposed for a new application, it would have realized AlloDerm's shortcoming for that use.
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> [Fantini Dutcher Cert., Ex. I, Billiar Report 22.]

Dr. Billiar opined that LifeCell failed to conduct sufficient testing and analysis of AlloDerm® to determine its appropriateness for use in ventral hernia repairs. Putting aside the typical requirement to prove a design defect using the traditional risk-utility analysis—including proof of a safer alternative design—Plaintiffs argue that LifeCell's failure to conduct appropriate testing and analysis of AlloDerm® prior to marketing for use in hernia repair is itself a design defect.

Plaintiffs' argument is without legal basis. A lack of testing or a flaw in the design process is not, standing alone, a design defect. Green v. General Motors Corp., 310 N.J. Super. 507, 529 (App. Div. 1998). As Defendant argues:

> The law is concerned with the product itself and whether it is safe, not whether any specific protocols were followed in making it. A product that has been through the most rigorous design process can be flawed and dangerous, and conversely, a product developed without a rigorous design process can be safe and effective.
>
> [Def.'s Foster Br. 6.]

The Green court criticized the jury charge regarding the defendant manufacturer's duty to inspect and test the product in that case. The court reasoned:

> It is clear that a breach of any duty to test, insofar as it may exist, is relevant to a negligence cause of action, or in a rare case to a manufacturing defect, but not a design defect claim. As defendant correctly notes, a product that is not defective and has not been tested at all remains free of a defect. Similarly, a defective product that has been extensively tested is still defective. Proof of a failure to test or of inadequate testing may be evidential as an explanation of why a design is defective, but it is not in itself proof of a separate basis for liability.
>
> [Green, supra, 310 N.J. Super. at 529.]

Plaintiffs' claim that LifeCell failed to properly test or analyze the properties of AlloDerm® before marketing the product for hernia repair does not, standing alone, prove a design defect. Thus, as previously discussed, to satisfy the burden of proving a design defect under the NJPLA, Plaintiffs are required to prove a safer alternative design existed at the time of their surgeries.

E. The Feasibility, Practicality, and Safety of a Proposed Safer Alternative Design are Determined According to the State of Technological Knowledge at the Date of Manufacture, Not the Date of Trial

Although Plaintiffs acknowledge that the practicality and feasibility of a proposed alternative design are judged according to the state of knowledge at the time of manufacture, Plaintiffs contend that "the relative safety of the alternative design is to be judged at the time of trial."[77] Plaintiffs' argument was rejected by the Supreme Court's decision in Lewis v. Am. Cyanamid Co., supra, 155 N.J. 544 (1998).

In support of this argument, Plaintiffs cite a single sentence in a pre-NJPLA design-defect case,[78] Crispin v. Volkswagenwerk AG, 248 N.J. Super. 540, 558 (App. Div. 1991). The sentence relied upon by Plaintiffs states that "[u]nder [the risk-utility analysis], a product is defective if a reasonable person would conclude that 'the magnitude of the scientifically perceivable danger as

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[77] Simineri Opp. 9.

[78] Although Crispin v. Volkswagenwerk AG was decided after the enactment of the NJPLA in 1987, the case was originally filed prior to passage of the NJPLA. See Crispin v. Volkswagenwerk AG, 248 N.J. Super. 540, 545-47 (discussing the "tortuous path" the case took leading up to the Appellate Division's opinion).

it is proved is to be at the time of trial outweighed the benefits of the way the product was so designed and marketed.'" Ibid. (quoting Cepeda v. Cumberland Engineering Co., Inc., 76 N.J. 152, 172-73 (1978)(emphasis in original)). The quoted section of the Crispin opinion is silent as to the time for determining the safety of a proposed alternative design. Rather, the quoted statement merely discusses the "perceivable danger" of the allegedly defective product.

The very question presented by Plaintiffs in this case was definitively answered by the New Jersey Supreme Court in Lewis v. Am. Cyanamid Co., 155 N.J. 544, 565 (1998). In Lewis, the Court determined that the practicality and feasibility of a proposed alternative "must be evaluated according to the state of knowledge at the time the [product] was manufactured, not at the time of trial. Id. at 568 (emphasis added). Although Plaintiffs attempt to separate the issue of safety from the issues of feasibility and practicality, the Court in Lewis clearly contemplated that the known safety or lack thereof of the proposed alternative design was encompassed by the feasibility and practicality analysis.

In Lewis, the plaintiff was injured when a can of insecticide spray ("fogger") exploded in his kitchen. Id. at 551. The plaintiff asserted that the fogger, which was manufactured in either 1988 or 1989, should have been designed to use the compound P-22 instead of the hydrocarbon propellant that led to the explosion because P-22 is less flammable. Id. at 552. As the Court in Lewis explained:

> Both plaintiff and defendants offered expert testimony regarding the practicality and feasibility of P-22 as an alternative design. Plaintiff's expert testified that P-22 was safe for use in the foggers and was three times less flammable than the hydrocarbon propellant. . . . In contrast, defendant's expert testified that P-22 was a teratogen, meaning it could cause birth defects. He explained further that P-22 eventually was phased out by the 1990 Amendments to the Clean Air Act because of its ozone-depleting qualities. Defendant's expert

> also stated that P-22 was too highly pressurized for safe use in the foggers.
>
> [Id. at 552 (emphasis added).]

The Lewis Court noted that "[t]o succeed on his design-defect claim, plaintiff was required to prove that a practical and feasible alternative design existed that would have reduced or prevented his harm." Id. at 560. The defendants in Lewis argued that the proposed alternative design was not safe for use based in part on knowledge acquired subsequent to the manufacture of the fogger. The plaintiff countered that the safety risks of the proposed alternative design were not actually proven at the time of manufacture. In Lewis, there was no dispute over whether it was technologically feasible to use P-22 as a propellant in the fogger. There was also no argument that P-22 was so prohibitively expensive so as to make it impractical. Nor was there any argument that the use of P-22 would have rendered the fogger ineffective for its intended purpose. The parties' only dispute was whether the safety risks of using P-22 as a propellant were known at the time of manufacture or whether they were established subsequent to the product's manufacture.

The Lewis Court determined that "the practicality and feasibility of P-22 as an alternative must be evaluated according to the state of knowledge at the time the fogger was manufactured, not at the time of trial." Id. at 568. It is clear from the Court's decision that the practicality/feasibility analysis necessarily encompasses the safety of the alternative design. The Court held that "[d]efendants in products liability actions should be judged not on what occurs in the future, but on what they knew or should have known at the time their products left their control." Id. at 573. Noting the incorporation of the state-of-the-art defense in the NJPLA, the Court in Lewis reasoned that "[b]ecause of this focus, a plaintiff cannot propose an alternative design that was not 'practical and technically feasible' at the time of the product's manufacture." Id. at 574 (quoting N.J.S.A. § 2A:58C-3(a)(1)).

The dispute in Lewis as to the feasibility and practicality of the plaintiff's alternative design turned on the safety of that design. Thus, the Court in Lewis held that the relative safety of the proposed alternative design must be evaluated according to the state of knowledge at the time the product is manufactured, not at the time of trial. Therefore, Plaintiffs are required to prove the existence of a feasible and practical safer alternative design according to the state of knowledge at the time of Plaintiffs' surgeries. Plaintiffs' burden includes proving that the alternative designs suggested by Plaintiffs were known to be safer at the time AlloDerm® was implanted into Plaintiffs.

F. Plaintiffs Have Failed to Produce Sufficient Empirical Evidence That Feasible and Practical Safer Alternative Designs Were Available

To support a *prima facie* case for design defect, Plaintiffs are required to put forward evidence that there existed a feasible and practical safer alternative design based on the state of knowledge at the time of their surgeries. Plaintiffs must present expert opinions demonstrating the existence of a safer alternative design. See Diluzio-Gulino, supra, 385 N.J. Super. at 437-38. "Expert testimony in conclusionary terms is insufficient to meet that burden." Id. at 438. Plaintiffs' experts must provide opinions "substantiated by empirical evidence, that 'the number of lives saved (or injuries avoided) by adopting [his] alternative design[] would be greater than the corresponding number of lives lost (or injuries sustained) as a result of such adoption'." Id. at 438-39 (alterations in original) (quoting Crespo v. Chrysler Corp., 75 F.Supp. 2d 225, 229 (S.D.N.Y. 1999).

Plaintiffs are not required "to provide a blueprint or build a prototype" and they may "demonstrate feasibility by showing that other manufacturers have incorporated" the proposed

design.[79] Rider v. Township of Freehold, Nos. A-2319-06T1 and A-2840-06T1, 2008 N.J. Super. Unpub. LEXIS 641 (App. Div. July 14, 2008). However, Plaintiffs are incorrect in stating that they need not provide "empirical evidence" to "establish that a proposed alternative design is safer."[80] While Plaintiffs may identify the defect and "suggest[] an alternative that eliminates or does not pose the same risk," Plaintiffs still must prove with empirical evidence or reliable data that the alternative is actually safer and that there was evidence it was safer at the time of manufacture. See Lewis, supra, 385 N.J. Super. at 570.

Plaintiffs cite an unpublished Appellate Division case in support of their claim that they need not provide empirical evidence that their proposed alternative designs were known to be safer at the time of manufacture. Rider v. Township of Freehold, Nos. A-2319-06T1 and A-2840-06T1, 2008 N.J. Super. Unpub. LEXIS 641 (App. Div. July 14, 2008). In Rider v. Township of Freehold, plaintiff brought a wrongful death claim after her husband died of "injuries when he struck his head against a utility pole that penetrated the door and intruded into the passenger compartment of his 1986 BMW 325i." Rider, supra, 2008 N.J. Super. Unpub. LEXIS 641, at *1.

Plaintiffs' reliance on the Rider case is misplaced. First, the Rider opinion is not binding on this court. Second, Rider is distinguishable from the present matter. In Rider, the court found that the expert testimony offered by the plaintiff was sufficient to sustain a jury verdict that the decedent's BMW was defective. Id. at *19. The plaintiff's experts offered alternative designs that would have created a protective cage around the passenger compartment of decedent's car, thus minimizing the intrusion of the utility pole into the compartment. Id. at *12. Plaintiff's experts also suggested stiffening the structure using baffle technology that had been tested by another

[79] Dutcher Opp. 17.
[80] Ibid.

company and demonstrated to be safer thirteen years prior to the manufacture of the decedent's car. Ibid. Plaintiff's experts further suggested the use of foam technology, the improved safety of which had also been demonstrated and reported approximately thirteen years prior the manufacture of the decedent's car. Id. at *13. Plaintiff's experts additionally suggested the insertion of a steel guardrail into the door of the BMW, technology that was recommended in a report by another company 18 years prior to the manufacture of the decedent's car. Id. at *14-15.

In Rider, although defendant BMW argued that the plaintiff "did not provide a blueprint, build a prototype or test the measures it proposed," the court held that a blueprint, prototype or test was not required. Id. at *19. The court reasoned that an "expert may demonstrate feasibility by showing that other manufacturers have incorporated that design." Ibid. The court also noted that the plaintiff's experts could rely on the results of tests conducted by others. Ibid. The court determined that:

> Quite obviously, the evidence adequate to support a finding that the alternative design proposed is safer, practical and feasible and would avoid or minimize the harm at issue will vary with the defect alleged and the solution proposed. Clearly, it is not enough to show that the design of the product caused the injury. But, empirical evidence establishing that the proposed alternative design is safer or a tested prototype is not essential in every case.
>
> [Id. at *19-20.]

The Rider court concluded that evidence required to prove a safer alternative design will vary depending on the circumstances of the case. Id. at 20. Notably, the plaintiff's experts in Rider relied on data from safety testing and studies conducted by other parties on technology that was the same or similar to the plaintiff's proposed alternatives. In finding that the plaintiff had produced sufficient expert testimony to demonstrate that safer alternative designs were feasible and known

to exist at the time the decedent's BMW was manufactured, the court distinguished the case of Diluzio-Gulino v. Daimler Chrysler Corp., supra 385 N.J. Super. at 440.

In Diluzio-Gulino, the plaintiff was injured in a car accident and alleged that her car's airbag settings were defective. Id. at 435. As the Diluzio-Gulino court explained:

> The dispute about Daimler's airbag focused on its settings for deployment and the Barrier Equivalent Velocity ("BEV") of plaintiff's car at impact. BEV is a term of art employed by all concerned, meaning, in essence, a speed at which a vehicle goes head on into a barrier, measured in miles per hour. Airbags are set to deploy at various BEVs. The BEV of a car in a particular accident is a complex question since collisions occur in all sorts of ways . . . .
>
> [Id. at 436.]

The court in Diluzio-Gulino held that the plaintiff's expert failed to provide sufficient evidence of an alternative safer design. Id. at 439. Although the plaintiff's expert testified that the airbag should have been designed with a higher BEV, the expert did not specify what that higher BEV should be and "admitted that he did not know how many more deaths would occur" and "none of the technical reports on which he relied provided specific data in support of any particular setting for low impact accidents." Id. at 437-48. The court found that "[a] plaintiff asserting a design defect in a products liability action 'must prove under a risk-utility analysis the existence of an alternate design that is both practical and feasible,' and 'safer' than that used by the manufacturer." Id. at 441 (quoting Lewis, supra, 155 N.J. at 571). While the plaintiff's expert in Diluzio-Gulino suggested the BEV should have been higher, the expert did not conduct any testing to determine the appropriate BEV or provide any data demonstrating what a proper BEV would be. Id. at 438-39. Thus, the Diluzio-Gulino court held that the plaintiff's expert failed to "present an opinion, substantiated by empirical evidence" that the proposed alternative was safer than the allegedly defective airbag. Ibid.

In distinguishing the Diluzio-Gulino case, the Rider court held that a more complex case requires more specific data:

> BMW relies on Diluzio-Gulino for the proposition that empirical evidence demonstrating that the alternative is safer is essential, but that case is distinguishable. At issue there was a claim that the setting for deployment of an airbag was too low – that is, triggered by an impact of too little force. The question whether an alternative higher setting for deployment of an airbag is 'safer,' by its very nature, requires a comparison of results under accident scenarios at *impacts between the manufacturer's setting and the setting* suggested. Without such evidence, there is no reasonable basis for a jury to conclude that an alternative and higher setting for deployment, which would prevent deployment across a range of lower impact accidents, is a safer design.
>
> The alternative design features proposed in this case are of a different sort. Plaintiff's experts did not recommend alternatives that eliminated protective measures.
>
> [Rider, supra, 2008 N.J. Super. Unpub. LEXIS 641, at *20-21 (emphasis added) (citations omitted)]

The court finds the analysis of safer alternative designs required in Diluzio-Gulino is applicable to the analysis required in Plaintiffs' cases. Plaintiffs are required to put forward empirical evidence or specific data demonstrating that their proposed alternative designs were not only technically feasible at the time of manufacture, but were safer and were demonstrated to be safer at the time of manufacture. See Diluzio-Gulino, supra, 385 N.J. Super. at 438-39.

Similar to the alleged defectively designed airbags in Diluzio-Gulino, which required consideration of the complex factors attendant to high speed car accidents, the design aspects of implantable biologic tissue grafts must account for complex and varying factors depending on the patient and the surgical procedure. See Diluzio-Gulino, supra, 385 N.J. Super. at 436. Several of the proposed hernia repair alternatives affect or diminish other safety aspects of biologic meshes. For example, one of Plaintiffs' proposed alternative designs, chemical cross-linking, while potentially increasing desirable characteristics such as strength and durability, has a deleterious

effect on other aspects, for example, by increasing the risk of foreign body response.[81] Thus, for a jury to determine that Plaintiffs' proposed alternatives are actually safer, empirical evidence is required to demonstrate the relative safety of Plaintiffs' proposed hernia repair alternatives in comparison to AlloDerm® as a hernia repair product.

Plaintiffs maintain that they have adduced "ample evidence that safer alternative designs of abdominal hernia repair grafts were both practical and feasible" at the time of Plaintiffs' surgeries.[82] Plaintiffs offer three proposed safer alternative designs: (1) processing xenografts (animal-based tissue) in the same manner as AlloDerm®; (2) optimizing AlloDerm® with cross-linking, thickness levels, or other mechanical preconditioning; or (3) cross-linked animal-based grafts. The court addresses each of Plaintiffs' proposed safer alternative designs.

i. Processing Xenografts in the Same Manner as AlloDerm®

Plaintiffs point to LifeCell's development and promotion of Strattice® as evidence that a safer alternative design option was to process animal-based skin in the same manner as AlloDerm®. Strattice®, an animal skin, is processed in essentially the same manner as AlloDerm®.[83] Strattice® is a non-cross-linked acellular graft made from pig skin. However, Strattice® was not approved by the Food and Drug Administration until June 2007 and was not commercially available until late 2007.[84] Thus, the only Plaintiff for whom Strattice® was a viable option was Mrs. Foster, who had her surgery in June of 2008.[85] The other Plaintiffs had their surgeries prior to the commercial availability of Strattice®.

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[81] Field Foster Reply Cert., Ex. F., Huckfeldt Dep. 166:3-23.
[82] Dutcher Opp. 19.
[83] Foster Opp. 15.
[84] Foster Opp. 17.
[85] Foster Opp. 6.

Plaintiffs cite a single article in support of their argument that Strattice® was a safer alternative design at the time of Mrs. Foster's surgery.[86] The cited article was a study conducted by Dr. Kristin Campbell and others of seventy-two guinea pigs, half implanted with AlloDerm® and the other half implanted with Strattice®.[87] The limited four-week study reported no infections and no recurrences in either of the test groups.[88] The Campbell study concluded that:

> [b]oth [AlloDerm] and [Strattice] become infiltrated with host cells and blood vessels within 4 weeks and have similar musculofascia-bioprosthetic interface strength. However, [AlloDerm] has greater cellular and vascular infiltration. Longer-term studies will help determine whether later differences in material strength, stiffness, and remodeling affect hernia repair and/or bulge incidence.
>
> [Ibid.]

Contrary to Plaintiffs' assertion, the Campbell study did not determine that "when AlloDerm is used in hernia repair it tends to stretch after implantation . . . which makes Strattice a more attractive alternative . . . ."[89] Rather, the article noted that:

> A major disadvantage of [AlloDerm], however, is its tendency to stretch after implantation, resulting in bulging of the repair site. The newer xenogeneic non-cross-linked porcine acellular dermal matrix [Strattice] may be an attractive alternative because, anecdotally and in the unpublished experience of our group, the bulge rate with [Strattice] appears to be negligible.
>
> [Id. at 2322 (emphasis added).]

Based on their own anecdotal experiences, the article's authors concluded that AlloDerm® has a tendency to stretch, and therefore, Strattice® "may" be an "attractive alternative."[90] This is not the kind of empirical evidence required to demonstrate that Strattice® was a feasible and safer alternative design at the time of Ms. Foster' surgery. Moreover, the article was not published until

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[86] Foster Opp. 16; Fantini Foster Opp., Ex. 35, Campbell article 2322.
[87] Id. at 2321.
[88] Ibid.
[89] Foster Opp. 16.
[90] Ibid.

2010. Therefore, even if the court assumes that the article supports Plaintiffs' proffer of Strattice® as a safer alternative to AlloDerm®, the article does not conclude that Strattice® was safer as of the time of Ms. Foster's surgery, just months after Strattice® was made commercially available.

Acknowledging that Strattice® was not commercially available until late 2007 at the earliest, Plaintiffs argue that LifeCell was "well aware of the practicality and feasibility of this alternate design by at least 2004" and cite to a study by Dr. Ronald Silverman included in AlloDerm®'s marketing materials.[92] The Silverman study compared the results of synthetic meshes with AlloDerm® grafts implanted in 22 Yucatan miniature pigs.[93] The article explained that the AlloDerm® used in the study was processed from pig skin rather than human skin "in order to avoid a xenogeneic response."[94] The purpose of the Silverman study was not to evaluate the use of animal-based grafts as an alternative to human-based grafts, but was intended to compare the results of allogenic (tissue harvested from the same species) grafts with synthetic meshes.[95] The study reported comparable outcomes between the pigs implanted with synthetic mesh and the pigs implanted with the pig-based AlloDerm® at six and nine months.[96] The Silverman study examined the use of AlloDerm® for hernia repairs:

> There have been several biologic materials available for use in the abdominal wall produced from xenogeneic sources, such as porcine intestinal submucosa. However, xenogeneic tissues, even when acellular, carry the risk of a slow immunologic rejection to the components of the tissues themselves. Xenogeneic [acellular dermal matrix] implants have been studied in an animal model and have been shown to illicit a longlasting humoral and cell-mediated immune response that adversely affected wound healing when compared to allogenic tissues.

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[92] Fantini Foster Cert., Ex. 36, AlloDerm® marketing materials.
[93] Fantini Foster Cert., Ex. 26, Silverman article at 336.
[94] Ibid.
[95] Ibid.
[96] Ibid.

[Id. at 341 (emphasis added).]

It is clear that the Silverman study was intended to research a potential solution to the apparent problem of immune responses resulting from the implantation of animal-based tissue grafts in humans. The researchers used pig skin because pigs were the animal being studied and the researchers wanted to avoid immune response problems. Based on this study, it cannot be said that LifeCell knew in 2004 that xenogeneic grafts were a safer alternative design for hernia repairs. The Silverman study simply demonstrates that surgeons were looking for a safer alternative to xenogeneic implants.

The court understands that Plaintiffs are critical of LifeCell's reliance on the Silverman study for the promotion of AlloDerm® in hernia repairs. However, those criticisms are irrelevant to Plaintiffs' burden of proving a feasible and practical safer alternative design. Given the nature and purpose of the Silverman study—to examine the use of allogenic tissues as a solution to the problems posed by xenogeneic tissues— the court disagrees with Plaintiffs that this study provides *prima facie* evidence "that safer alternative designs had been tested, but not incorporated, into the production of AlloDerm . . . ."[97]

Plaintiffs note that both of their design defect experts "have opined that a porcine (pig) skin processed in the same manner as AlloDerm was a safer alternative design that was both feasible and practical in June 2008."[98] Dr. Billiar discussed the Silverman study in his expert report and explained the reasons he believes "the porcine version of AlloDerm is superior for the hernia repair application."[99] Dr. Billiar's report concluded that "[o]ther reasonable safer designs existed at the time AlloDerm was being marketed for ventral/incisional hernia repair including . . . xenogeneic

[97] Foster Opp. 16.
[98] Foster Opp. 15.
[99] Fantini Foster Cert., Ex. 44, Billiar Report 20.

decellularized tissues such as Strattice which is stronger and stiffer than AlloDerm."[100] At his deposition, Dr. Billiar conceded that he had done no testing on Strattice® and had seen no literature comparing AlloDerm® with Strattice®:

> Q. Okay. You also say later on in that paragraph, "If LifeCell had truly evaluated the application for hernia repair, it is apparent they would have realized their porcine version of AlloDerm (Strattice) was actually the better product for this application."
>
> Are you referring to the pig AlloDerm Dr. Silverman used, or are you referring to the Strattice commercial product that became available in 2008?
>
> A. In this case I am referring to – that a porcine version of AlloDerm, because of the properties of the pig material and the ability to have more reproducibility with it. And my understanding is that from what we were talking about today, that the differences in being able to – well, I was talking about a porcine version of AlloDerm and I wasn't separating the two. I didn't know that – I did not know the differences in processing between the two.
>
> Q. Have you tested either product, the pig AlloDerm or the Strattice?
>
> A. I have not tested the pig AlloDerm or the Strattice in the laboratory.
>
> Q. Have you ever seen any head-to-head comparison that studied – I mean head-to-head study that compared AlloDerm to Strattice?
>
> A. In terms of a clinical study or in terms of a mechanical analysis?
>
> Q. Either one.
>
> A. From my reading, I'm not sure I've seen head-to-head. I don't recall seeing a head-to-head comparison, but I definitely saw differences in mechanical properties between the two.
>
> Q. And what is your basis for saying that you believe the porcine version of AlloDerm is better than AlloDerm for use in hernia repair?
>
> A. The porcine version was – well, the literature I read about pig-based decellularized skin was that it had a lower elastin content and so it didn't stretch out as much. And there haven't been, according to what I've read there haven't been cases of the pig-based decellularized skin stretching out and causing reherniation.

[100] Id. at 22.

> Q. Do you know whether that's a result of improvement in surgical technique or not?
>
> A. I don't know the reasons for why. It could be that with Strattice they had better – they gave more clear instructions on what the surgical technique should be, and they've learned over time based on the clinical work.
>
> Q. But you don't know one way or the other?
>
> A. I don't know what the reasons were.[101]

When Plaintiffs' other design defect expert, Dr. Huckfeldt, was asked what alternative materials LifeCell could have used, he also referenced LifeCell's development of Strattice®:

> Q. . . . You say that "LifeCell failed to use safer alternative materials and methods." What alternative materials do you believe are safer – that would have been safer for LifeCell to use than AlloDerm?
>
> A. The ability to create a product like they did with Strattice coming from a pig instead of a human where you can control factors that they could not control with AlloDerm and that they knew they could not control with AlloDerm: age, genetic issues within the patient, collagen vascular disorders within the patient potentially. All of those things were uncontrollable in human tissue, as well as size as well as a variety of things. They are very well controlled using animal products. They started – I mean, Dr. Silverman shows in his study, in fact, that porcine AlloDerm – the equivalent of porcine AlloDerm is easy to create, is very creatable. So LifeCell knew that they had other options rather than just human tissue.[102]

Strattice® was not available until late 2007. Plaintiffs' experts believe that LifeCell should have developed Strattice® earlier. However, the basis for Plaintiffs' experts' opinion that early development of Strattice® was feasible appears to be Dr. Silverman's use of a pig-based version of AlloDerm® in a study that was not intended to examine the use of animal-based grafts in humans. The Silverman study does not provide the level of empirical evidence necessary to demonstrate that "processing xenograft skin . . . in the same manner as AlloDerm" was a feasible or practical or safer alternative design option at the time of Plaintiffs' surgeries. At best, the

[101] Field Foster Cert, Ex. O, Billiar Dep. 248:9-250:17.
[102] Fantini Foster Cert., Ex. 41, Huckfeldt Dep. 265:5-24.

Silverman study may have suggested that the use of xenogeneic grafts processed in the same manner as AlloDerm® might in the future be a potentially feasible alternative to synthetic meshes. However, the Silverman study does not demonstrate that such an alternative was feasible or practical or safer at the time of Plaintiffs' surgeries. Nor does Plaintiffs' theory take into account the time required for the requisite FDA-approval process for porcine graft products.

Even Ms. Foster, whose surgery occurred after Strattice® became commercially available, is unable to proffer any empirical evidence that Strattice® provides a safer alternative to AlloDerm®. Although the availability of Strattice® at the time of Ms. Foster's surgery may demonstrate that it was a technologically feasible alternative, Ms. Foster has not produced any evidence that Strattice® was actually proven to be safer than AlloDerm® for use in hernia repairs at the time of her surgery. The only evidence offered is the conclusory opinions of Drs. Huckfeldt and Billiar that Strattice® is safer and a single 2010 article written by Dr. Campbell anecdotally suggesting non-cross-linked porcine acellular dermal matrix may provide an "attractive alternative."[103] The Campbell article concluded that although both AlloDerm® and Strattice® have similar pre-operative strength, AlloDerm® "has greater cellular and vascular infiltration" but "[l]onger-term studies will help determine whether later differences in material strength, stiffness, and remodeling affect hernia and/or bulge incidence."[104] Thus, even the single study authored by Dr. Campbell and proffered by Plaintiffs as comparing the two hernia repair alternatives failed to definitively conclude that one product is safer or more effective than the other product.

[103] Campbell article 2322.
[104] Id. at 2321.

ii. Optimizing AlloDerm® with Cross-Linking, Thickness Levels, or Other Mechanical Preconditioning

Plaintiffs argue that another alternative design option was for LifeCell to "optimize" AlloDerm® through the use of cross-linking or by better controlling thickness levels.[105] Cross-linking refers to chemically treating the biologic graft in order to link together the proteins in the tissue, thus increasing the strength of the graft.[106] Both of Plaintiffs' design experts discussed the potential use of cross-linking as a safer alternative design.

Dr. Billiar's expert report explains cross-linking and his own research on the use of cross-linking, noting that "[t]he extent of crosslinking may be tailored for optimal remodeling in different applications (load bearing vs. space filling, etc.)."[107] Later in his report, Dr. Billiar criticizes LifeCell's lack of testing and research into cross-linking for AlloDerm® and notes that although LifeCell was apparently concerned with the immune response that can be induced by cross-linked biologic materials, "crosslinking is not an all or nothing proposition. The level of crosslinking can be tailored."[108] However, Dr. Billiar is unable to provide any concrete information on how or to what extent AlloDerm® could be cross-linked to improve the product or make it safer. Dr. Billiar merely speculates that testing should have been conducted to appropriately tailor the level of cross-linking in AlloDerm®. At his deposition, Dr. Billiar conceded that he had no specific data to determine the amount of cross-linking or other processing necessary to optimize AlloDerm®:

> A. When those studies -- if those studies were done on crosslinking of other physical -- so there is crosslinking, we're speaking of chemical. There is also physical crosslinking. There is other physical manufacturing processes that can [be] used.

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[105] Foster Opp. 17.
[106] Huckfeldt General Report 5.
[107] Billiar Report 7.
[108] Id. at 13.

When those were tested, my opinion is that you would have a better product at the end of that testing by optimizing those parameters.

Q. So you would do a bunch of tests and you may end up using one or more of the different techniques, but you can't say for sure that you would use all of them?

. . . .

Q. Is that a fair characterization of what you just said?

A. In the end, after doing different types of processing, just like they did to determine what they consider their optimal decellularization process. There are many different decellularization processes. There is many different crosslinking and physical manipulations of the base material which is skin, decellularized. It's not fascia. It's not any other material. It's a decellularized skin. And that cannot be expected to work in an application that is – in any application without doing testing and optimizing of that material.

Q. So do you believe it's necessary to do chemical crosslinking to improve the performance of AlloDerm?

. . . .

A. I believe –

. . . .

A. I personally have –

. . . .

A. – not done testing of optimization of what LifeCell should do to determine the best product that they can make in my own lab. That is not what I consider – that is not what I've been asked to do. LifeCell needs to optimize their product for an application that they want to market it for.

Q. I understand that you believe that AlloDerm hasn't optimized its product. My question is whether you formed any opinions as to what would be required to optimize the product.

A. I believe some combination of physical and chemical modifications would be necessary. Crosslinking is one of those potential, and there is many different kinds of crosslinking. There isn't just such as a glutaraldehyde heavily crosslinked. Glutaraldehyde is a crosslinking agent.

There are many different types of crosslinking of different degrees. There are many different physical, such as we talked about earlier, of preconditioning or pretensioning to a known amount. There are

> different thicknesses that can [be] used. There are many different processing techniques that can be used to optimize what is starting as a base material that's decellularized skin, not fascia, not actual skin, but a decellularized version of skin.
>
> . . . .
>
> Q. Have you made any determination of the optimal amount of crosslinking that should be done to AlloDerm?
>
> A. I have not made a determination of the optimal amount of crosslinking that should be made to AlloDerm, no.[109]

In essence, Dr. Billiar's opinion is that cross-linking had the "potential" to make AlloDerm® a more efficacious or safer product, but he did not determine how that would be accomplished. Dr. Billiar criticizes LifeCell's testing and design process. As previously discussed, lack of testing is not itself a design defect. Plaintiffs must present more than speculation that some unidentified amount of cross-linking may have made AlloDerm® a safer alternative product.

Dr. Huckfeldt also opined that cross-linking was a safer alternative design for AlloDerm®. In his report, Dr. Huckfeldt stated:

> **2. LifeCell was aware that cross-linking and other techniques were available to customize the strength of AlloDerm grafts for abdominal wall pressures**
>
> Tissue matrices are designed to allow tissue regeneration. There are numerous tissues on the market used in multiple medical indications for this purpose. In my practice alone, acellular dermal templates were used in hernia repair, buttress application during repair of bowel injury, nerve/vessel reinforcement and topical wound repair. Cross-linking is a well-known option in the preparation of dermal matrices. Cross-linking involves the use of a chemical processes to support the strength of collagen, elastin and other extracellular compounds. LifeCell opted to not utilize this technology to strengthen their product.[110]

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[109] Field Foster Cert., Ex. O, Billiar Dep. 106:6-109:20.

[110] Field Dutcher Cert., Ex. L, Huckfeldt General Report 11-12 (emphasis in original).

However, as Dr. Huckfeldt conceded at his deposition, although his report opines that cross-linking biologic grafts was a known and feasible design option at the time of Plaintiffs' surgeries, he could say whether cross-linked materials are necessarily safer or more effective than non-cross-linked materials in all cases. Additionally, Dr. Huckfeldt acknowledged that cross-linking may have a detrimental effect on other design aspects of a tissue graft:

> Q. And you say that the cross-linking may have allowed significant healing and wound strength; correct?
>
> A. Correct.
>
> Q. Why do you use the word "may" rather than "would" or "does"?
>
> A. Because I don't have any study that tells me that it's going to extend it long enough to make a functional difference in the abdomen replacing fascia. That's why we don't have the data for this study.
>
> Q. So you don't know whether cross-linking would help at all?
>
> A. I know it's going to – I know that cross-linking is going to delay the degradation. Will it delay it long enough is the question, and how much cross-linking do you need to determine whether that's going to happen or not, what degree do you need to cross-link the tissue. That would require an actual study that looked at it over a several month – many, many month time period to determine did this make a difference, and if no, how much more cross-linking do I need and is it worth it.
>
> Q. And would it result in detrimental effects as well?
>
> A. Absolutely.
>
> . . . .
>
> Q. Is it your opinion, Dr. Huckfeldt, that cross-linked biologic grafts perform better than non-cross-linked biologic grafts?
>
> A. It is my opinion that cross-linked grafts perform differently than non-cross-linked biologic grafts, and it depends on what your intent and your purpose is in your wound that you're trying to heal. I do believe that there are times where a cross-linked graft is going to last longer – that the detrimental risks of perhaps having more scar is better, yes. I do believe there are times where a non-cross-linked

> tissue may be better as well. So I don't think you can say one is better than the other. [111]

Although Dr. Huckfeldt opined that cross-linking was an "available" alternative design choice for AlloDerm®, he conceded that cross-linked grafts are not necessarily safer or more effective than non-cross-linked grafts in all cases and that studies were needed to determine the amount of cross-linking necessary to improve the durability of AlloDerm®.

Like the plaintiff's expert in Diluzio-Gulino, who speculated that the airbag BEV should have been set higher but did not have any data to support their opinion, Plaintiffs' belief that LifeCell should have done some amount of cross-linking and should have done more testing to determine the appropriate level of cross-linking is insufficient to demonstrate a safer alternative design. Plaintiffs must provide empirical evidence demonstrating that a specific amount and type of cross-linking would actually make AlloDerm® a safer product. This is especially so given that cross-linking is known to reduce other beneficial aspects of tissue grafts, for example, by increasing the risk of foreign body response. Plaintiffs must do more than demonstrate that cross-linking was a technologically feasible design option. Plaintiffs must proffer empirical evidence demonstrating that it is a safer alternative. This is particularly so because the proposed alternatives necessarily diminish other safety aspects of AlloDerm®. See Rider, supra, 2008 N.J. Super. Unpub. LEXIS 641, at *21.

Plaintiffs' experts believe that LifeCell also should have optimized the thickness or other properties of AlloDerm®. Dr. Billiar opined that LifeCell failed to properly analyze the loads on the abdominal wall to determine the strength needed to support the abdomen.[112] Dr. Billiar also criticized LifeCell for failing to control for graft thickness and not pursuing studies on layered

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[111] Field Foster Cert., Ex. D, Huckfeldt Dep. 251:18-253:12 (emphasis added).
[112] Field Foster Cert., Ex. N, *Billiar Expert Report* 12.

grafts.[113] In sum, Dr. Billiar's opinion is that LifeCell should have conducted more testing and analysis to determine an optimal thickness and mechanical preconditioning of AlloDerm® for use in hernia repairs. However, Dr. Billiar himself conducted no such testing and was unable to provide any specific data or evidence that thicker or preconditioned AlloDerm® would provide a safer or more effective product. At his deposition, Dr. Billiar discussed his opinion that LifeCell should have done testing to determine the optimal thickness of AlloDerm®, but conceded that he had done no such testing and his belief that thicker AlloDerm® would be more efficacious was essentially speculation:

> A. . . . .
>
> As you mentioned a few questions ago, if you start at a higher thickness, you start at a higher strength, you get less dissension. It's, again, a structurally stiffer material. So that seems like a very good design parameter to study.
>
> Q. To study. But you haven't made a determination yourself that AlloDerm is not thick enough, right?
>
> A. It's more likely than not that if they study the thickness of AlloDerm, they would find that thicker material is better for heavier patients and reduce thinning.
>
> Q. But nobody will know that unless the studies are done, right?
>
> A. Unless the studies are done, it can't be determined what the optimal thickness is.
>
> Q. And so you don't know what the optimal thickness is of AlloDerm, right, as you sit here today?
>
> A. It's more likely than not if those studies were done, they would find an optimal thickness.
>
> Q. But you don't know what that thickness would be?
>
> A. Without doing the studies, which they did not do, it's impossible to determine what the thickness – optimal thickness would be
>
> Q. But I'm asking you, you don't know what that thickness would be right now as you're sitting here, right?

[113] Ibid.

> A. I personally have not done the studies. So I cannot say what the thickness should be.[114]

Similarly, Dr. Billiar testified that while he believes LifeCell should have done more studies to determine the optimal amount of mechanical preconditioning necessary to make AlloDerm® appropriate for hernia repairs, he did not know what level of preconditioning was appropriate or even whether any amount of preconditioning would be appropriate:

> Q. . . . Have you made any determination as to what the optimal amount of mechanical preconditioning is to optimize AlloDerm for use in hernia repair?
>
> A. I have not done mechanical testing on AlloDerm to determine its optimal preconditioning, but they – I believe my opinion is that they should.
>
> Q. But you haven't made that determination yourself?
>
> A. Without me doing testing. If the testing were done, it would yield the optimal level, but I have not done the testing.
>
> Q. Then the optimal level might be zero, right?
>
> A. There are many possibilities of what it would be. AlloDerm – preconditioning or pretensioning of AlloDerm, the optimal condition could be zero.[115]

Again, Dr. Billiar believes that LifeCell should have done more testing to develop a safer alternative design but cannot confirm what that testing would reveal or provide any empirical data demonstrating what level of thickness or preconditioning would actually result in a safer product. Plaintiffs' belief that LifeCell should have done more testing to optimize the various design features of AlloDerm® is insufficient, without more, to demonstrate a feasible safer alternative design.

iii. Cross-linked animal-based grafts

[114] Field Julien Cert., Ex. O, Billiar Dep. 222:3-223:12 (emphasis added).
[115] Id. at 109:15-110:15.

Finally, Plaintiffs posit that cross-linked animal-based grafts provided a safer alternative design.[116] Plaintiffs' design defect experts opined that Permacol® was one such safer alternative design.[117] Permacol® is a cross-linked porcine-skin-based product that has been commercially available since 2002.[118] The commercial availability of Permacol® at the time AlloDerm® was being marketed for use in hernia repair demonstrates that cross-linked animal-based grafts were a technologically feasible alternative, but Plaintiffs must also proffer evidence from which a jury could determine that these products provided a safer alternative.

At his deposition, Dr. Billiar stated that Permacol® provided a safer alternative design at the time of Plaintiffs' surgeries. However, when asked to provide a basis for his opinion that cross-linked animal-based grafts provided a safer alternative design, Dr. Billiar cited three studies that all post-date the Plaintiffs' surgeries:

> Q. So apart from Permacol, can you identify any other product that you believe was a reasonable safer design than AlloDerm?
>
> A. When Strattice came out, I believe it's better.
>
> Q. But prior to Strattice coming out, it was Permacol? That's the only one?
>
> A. Permacol as a decellularized xenograft. That's the only one that comes to mind. And I believe in the Beale study there was one other that had a lower – they had a lower recurrence rate of another material. But that's a more recent study.
>
> . . . .
>
> Q. Do you know whether Permacol did anything more than – the makers of Permacol did any more testing than LifeCell did before putting its product on the market?
>
> A. I don't know what the makers of Permacol did. I don't have that data, and that's not the point of this – my analysis.

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[116] Foster Opp. 18.
[117] Ibid.
[118] Ibid. Fantini Foster Cert., Ex. 7, History of Biologic Prostheses.

> Q. Did you identify it as a reasonable safer design, Permacol? You just did, right?
>
> A. Yes.
>
> Q. But you don't know whether they did any more testing than LifeCell did?
>
> A. I don't know.
>
> . . . .
>
> Q. And what were the names of those studies, if you can recall those?
>
> A. I believe one or two are in here, but there is the Beale study, which I've mentioned a few times. Beale. Bellows. I relooked at some of the articles that are on here, and there is a Slater article.
>
> Q. Okay.
>
> A. Those three in particular I looked back at for clinical side.
>
> Q. And just for the sake of counsel on the record, what was the essence of those articles and why did you look at them?
>
> A. I was looking back at the clinical – the clinical behavior or recurrence rate for different biological materials and I found that AlloDerm, as we've been saying earlier, had a higher recurrence rate than other biological material.[119]

Plaintiffs rely on these same studies as evidence that cross-linked animal-based grafts provided a safer alternative to AlloDerm®.[120] The Bellows study was a review of a number of retrospective studies of biologic graft outcomes that specifically recognized its own limitations:

> The use of this review is limited for a number of reasons. First, there was tremendous heterogeneity of the published literature. The selection of patients, severity of hernia, medical comorbidities, surgical technique, type of material used, and manner in which the material was implanted were all widely variable and <u>therefore interpretation of specific covariates on their individual impact on outcomes is difficult and probably not feasible</u>.[121]

[119] Field Foster Cert., Ex. O, Billiar Dep. at 251:17-253:1, 255:10-256:4.
[120] Foster Opp. 19.
[121] Fantini Foster Cert., Ex. 33, Bellows article 97.

Putting aside the recognized limitations of the Bellows study, and even assuming that Plaintiffs are correct in averring that this study demonstrates higher recurrence rates for AlloDerm® as compared to other products such as Permacol®, this article was published in 2013. Therefore, this article is incapable of showing that cross-linked animal-based grafts were a known safer alternative at the time of Plaintiffs' surgeries.

The Beale study was also a systematic review of retrospective incisional hernia studies.[122] That study concluded, "allograft acellular dermal matrix does have a significantly higher recurrence rate as compared with xenograft." However, the Beale study also noted:

> [a]n additional shortcoming of the analysis in this article is the large number of human biologic mesh repairs (AlloDerm®) that are compared with a much smaller cohort of xenograft biologic mesh repairs (Surgisis® and Permacol®). This highlights the paucity of data on these biologic devices and draws from older studies, which were performed primarily with the allograft products.[123]

Again, even disregarding the noted shortcomings in the Beale study and accepting the study as showing that cross-linked animal-based biologics are now known to be a safer alternative to AlloDerm®, the Beale study was not published until 2012, several years after the Plaintiffs' surgeries. Additionally, the Beale article recognized the historical lack of reliable empirical data assessing the relative safety and efficacy of animal-based tissue grafts compared to human-based grafts. Thus, the article provides no support for Plaintiffs' argument that these grafts were known to be a safer alternative at the time of Plaintiffs' surgeries. Similarly, the Slater article mentioned by Dr. Billiar at his deposition was not published until 2013, well after Plaintiffs' surgeries.[124]

[122] Fantini Cert., Ex. 32, Beale article 510.
[123] Id. at 516 (emphasis added).
[124] Fantini Foster Cert., Ex. 34, Slater article.

Dr. Huckfeldt's opinion that Permacol® or other cross-linked animal-based grafts provided a known safer alternative is similarly unsupported by the kind of empirical evidence necessary to prove a safer alternative design. Although Dr. Huckfeldt anecdotally opined that by June of 2008, he believed Permacol® was a known safer alternative, he was unable to cite any medical literature or other empirical data showing that Permacol® or any other animal-based graft was safer than AlloDerm®:

> Q. Yeah. Was there any literature, published studies, or other information out there in 2005 that informed the implanting surgeon that Surgisis, Permacol, or SurgiMend would have been safer and more effective than AlloDerm?
>
> A. Not to my knowledge.
>
> Q. Independent of what was in the information out there, in April of 2005, was it your opinion that Surgisis, Permacol, or SurgiMend were safer and more effective than AlloDerm?
>
> . . . .
>
> A. In April of 2005, I did not have any reason to believe from my knowledge that there was a difference in the outcome of any of those products.[125]

Dr. Huckfeldt also conceded that he could point to no published reports or other literature as of June 2008, the time of Ms. Foster's surgery, demonstrating that the cross-linked animal-based products were known to be a safer alternative to AlloDerm®:

> Q. . . . . So now we're at the same questions we had on Dutcher but using June of 2008 –
>
> A. Correct.
>
> Q. – as the time frame. Were there public literature, studies, information out there for the implanting surgeon that would identify animal-based tissues other or in addition to SurgiMend which you identify?

[125] Fantini Foster Cert., Ex. 41, Huckfeldt Dep. 373:18-374:12.

A. There were – other products by 2008 had begun to grow even farther. So, for example, CollaMend I think was released in 2006 or 2007, and I believe there was even another one in 2007 that was on – that at that point were on the market. So you still had Surgisis. You still had Permacol. You still had SurgiMend. You now at least had CollaMend, and I believe there was a fifth.

Q. And did any of the literature out there discuss a comparison of those products that you just identified in June of 2008 that opined that those products were safer or more effective than AlloDerm?

A. Not to the best of my knowledge, no, sir.

Q. And as of June of 2008, did you hold an opinion that those five products that you've just identified were safer and more effective than AlloDerm?

A. In my opinion by June of 2008, the use of Permacol had less recurrence in my practice because I had stopped using AlloDerm in 2006 because of the near 100% failure that we were now seeing coming back to the clinic.

Q. And how about the other four products other than Permacol? Did you hold an opinion that they were also safer and more effective than AlloDerm as of June 2008?

A. I had used SurgiMend but not enough to really be able to say one was better than the other for long-term outcomes.

Q. Okay. And how about Surgisis?

A. I had such limited experience with Surgisis.

Q. So no opinion?

A. No opinion.

Q. And CollaMend?

A. I've never used CollaMend.

Q. And there was another one that you didn't give me the name, but you said it came out in 2007.

A. And I didn't use it either.[126]

Dr. Huckfeldt further testified that the number of times he used Permacol® "was not huge either."[127] Thus, Dr. Huckfeldt's opinion that Permacol® provided a safer alternative design as of

[126] Id. at 374:21-376:14.
[127] Field Foster Reply Cert., Ex. F, Huckfeldt Dep. 61:1-11.

2008 is based on nothing more than his own limited anecdotal experience. Dr. Huckfeldt was unable to provide any empirical data demonstrating that Permacol®, or any other animal-based alternative, was proven to be safer than AlloDerm® as of the time of Plaintiffs' surgeries.

In sum, Plaintiffs' experts opined that a safer alternative design for AlloDerm® could theoretically have been determined if LifeCell had conducted additional testing and analysis. To the extent that other biologic products were available, Plaintiffs' experts were unable to point to any contemporaneous empirical evidence that those products were known to be safer at the time of Plaintiffs' surgeries. "Defendants in products liability actions should be judged not on what occurs in the future, but on what they knew or should have known at the time their products left their control." Lewis, supra, 155 N.J. at 573.

III. Conclusion

Under the NJPLA and New Jersey case law, Plaintiffs are required to proffer evidence that a feasible and practical safer alternative design existed at the time of manufacture, or for the purposes of Defendant's motions, at the time of Plaintiffs' surgeries. Plaintiffs must demonstrate that their proposed safer alternatives were not only technically feasible and practical, but were also known to be safer according to the state of knowledge at the time of manufacture. Expert opinions regarding the feasibility and safety of the proposed alternatives must be presented, and the experts' opinions must be substantiated by empirical evidence that the proposed alternatives would actually reduce the risk of injury. Diluzio-Gulino, supra, 385 N.J. Super. at 438-39.

Because the court finds that Plaintiffs have failed to proffer any reliable empirical evidence or data to form a reasonable basis on which a jury could determine that any of their proposed alternative designs were known to be feasible, practical, and safer according to the state of

knowledge at the time of Plaintiffs' surgeries, Defendant's motions for summary judgment as to Plaintiffs' claims for design defect are **GRANTED**.

8/14/15

JESSICA R. MAYER, J.S.C.